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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/632,741 | 08/04/2000 | Brent Belding | ACS-53498(21061) | 2770 |

24201 7590 01/27/2004
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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

13

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/632,741

Applicant(s)

BELDING ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 and 65-70 is/are pending in the application.
4a) Of the above claim(s) 6,7,10,12,27,29 and 39 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5,8,9,11,13-26,28,30-38,40-44 and 65-70 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 04 August 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.
37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s) _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

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DETAILED ACTION

Response to Amendment

1. The amendment filed 11/12/03 has been entered as Paper No. 11. The changes made to the claims have been approved by the examiner. Claims 1-44 and 65-70 are currently pending. Claims 6, 7, 10, 12, 27, 29 and 39 remain withdrawn from consideration for being drawn to a non-elected species. The claims being considered for further examination on the merits are 1-5, 8, 9, 11, 13-26, 28, 30-38, 40-44 and 65-70.
2. The declaration filed on 11/12/03 (entered as Paper No. 12) under 37 CFR 1.131 has been considered but is ineffective to overcome the Hanson (USPN 6,432,130) reference.
3. The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Hanson reference. The evidence does not disclose that the sheath is configured to “retract” or “rupture into portions which retract”, which is required by independent claims 1, 18 and 35. Also, the evidence does not disclose that the sheath includes a “plurality of circumferential perforations”, which is required by independent claims 3, 20 and 36. The evidence does not disclose the means for retaining proximal end being “secured to the proximal end portion of the means for delivering”, which is required by independent claim 23. The evidence does not disclose that the sheath is disposed “completely over the endoprosthesis”, which is required by independent claim 65. In addition, the evidence does not provide any written disclosure or disclosure in the form of drawings that shows an expandable member/means for expanding/balloon associated with the

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distal end portion of a catheter/means for delivering/catheter tube, which is required by every independent claim.

4. In showing actual reduction to practice for an article of manufacture, it is required that the invention be completed in operative form (completely manufactured) showing practical utility in the intended field of use. Tests are required and must be under either actual working conditions or laboratory conditions that duplicate actual working conditions. The tests must show utility beyond the probability of failure and the results must be reproducible. Because the evidence indicates in part 5(c) that the current stage of development at the time of the evidence was "Prototyping stage", it is concluded that the article was not completely manufactured and tested to meet the required threshold. Therefore, actual reduction to practice was not met at the time of the evidence.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5, 8, 9, 13, 16-26, 30, 31, 33-36, 40, 41, 43, 44 and 65-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanson (USPN 6,432,130, cited in previous office action).

Hanson discloses a fully sheathed balloon expandable stent delivery system with all the elements of claims 1, 3, 18, 20, 23, 35, 36 and 65. See abstract, Figures 1-5 and columns 2-3,

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lines 64-12 for a catheter assembly (10) for delivering an endoprosthesis within a body lumen including a catheter (14) having proximal and distal end portions, an expandable member (16) associated with the distal end portion of the catheter, an endoprosthesis (12) disposed on the expandable member, and a sheath (30) disposed on the catheter and over the endoprosthesis, wherein the sheath is configured to rupture into portions during expansion of the expandable member and retract towards first and second ends of the stent after rupturing to expose the endoprosthesis. The sheath includes a plurality of circumferential perforations (Figure 3 and column 4, lines 22-28). The sheath has a proximal end secured to the proximal end portion of the catheter and a distal end secured to the distal end portion of the catheter (column 2, lines 39-40). The sheath is also disposed completely over the stent (Figure 2).

Claims 2, 19 and 67, see column 4, lines 22-26 for weakened section.

Claims 4, 5, 21, 22, 24, 68 and 69, see column 2, lines 39-40 and 66-67 for stretching and securing sheath.

Claims 8, 9, 25 and 26, see column 2, lines 35-38 for expandable member being an inflatable dilatation balloon and endoprosthesis being a stent.

Claims 13, 30 and 40, see column 4, line 16 for sheath being formed from an elastomeric material.

Claims 16, 17, 31, 33, 34, 41, 43 and 44, see column 5, line 14 for sheath being formed from polyurethane.

Claim 66, see abstract and Figure 5 for sheath being configured to rupture into portions which retract towards the first and second ends of the stent after rupturing to expose the stent.

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Claim 70, see column 4, lines 22-26 for sheath including plurality of perforations, which allow the sheath to rupture during expansion of the balloon.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 11, 28, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson in view of applicant's own admission.

Hanson discloses a fully sheathed balloon expandable stent delivery system with all the elements of claims 1, 18 and 35, but is silent to the additional limitation of the catheter including an over-the-wire intravascular catheter, as required by claims 11, 28, 37 and 38. Applicant admits that an over-the-wire catheter is old and well known in the art on pages 20-21, lines 26-2 and Figure 8 of the specification. Because this type of catheter is standard in the art, it would have been obvious for the stent delivery system of Hanson to include an over-the-wire catheter. In addition, it appears from Figures 1-5 of Hanson that the catheter could include an over-the-wire intravascular catheter. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the catheter include an over-the-wire intravascular catheter because Applicant has not disclosed that an over-the-wire intravascular catheter provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's

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invention to perform equally well with other catheters because the ability for the sheath to rupture during expansion of the expandable member is not affected by the type of catheter used. Therefore, it would have been an obvious matter of design choice to modify Hanson to obtain the invention as specified in claims 11, 28, 37 and 38.

9. Claims 14, 15, 32 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson in view of Makower et al. (USPN 6,302,875 B1 as cited in previous office action).

Hanson discloses a fully sheathed balloon expandable stent delivery system with all the elements of claims 1, 18 and 35, but is silent to the additional limitation of the sheath being formed from polyurethane with a shore hardness of 45D or lower or a biodegradable material, as required by claims 14 and 15, 32, 42, respectively. Makower et al. teaches a catheter with a sheath formed from polyurethane having a shore hardness of less than 45D or a biodegradable material, elastin, in order to impart a less rigid and less hard region in the sheath. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Makower et al. to make the sheath of Hanson of a polyurethane having a shore hardness of less than 45D or a biodegradable material in order to impart less rigid and hard characteristics to the sheath so that it will expand with less pressure. See column 7, lines 9-28.

Conclusion

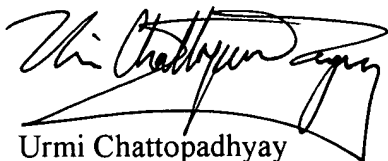
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

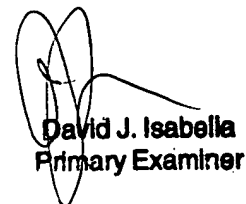
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner